



## **Question B6:**

**“Are bilateral animal models of infected bone defects ethical?”**



# 3rd Meeting of the International Consensus Meeting

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## RATIONALE

- IACUC (Institutional Animal Care and Use Committee)  
UNIFORMITY AND SCIENTIFIC EXPERTISE?
- NO VALIDATED INFECTED BILATERAL MODELS OTHER THAN WAR WOUND MODELS.
- LESS THAN 5% OF STUDIES ADHERE TO STANDARDS FOR SCIENTIFIC RIGOR : HISTOLOGICAL OUTCOMES? Jensen et al 2019
- DEFINED END POINTS, BIOBURDEN, ANTIBIOTICS ETC...



- ADVANTAGES/DISADVANTAGES OF BILATERALITY?
- ANIMAL NUMBERS VERSUS WELFARE
- INTRA ANIMAL CONTROLS
- ASSESSING “LAMENESS” RECUMBANCY IN INJURED ANIMAL?
- WHICH BONES ? SINGLE OR ONE OF TWO? i.e. FEMUR OR RADIUS/FIBULA.



- SYSTEMATIC REVIEW AS PER PROTOCOLS. COVIDENCE.
- CONTRIBUTORS ALSO INCLUDED PAPERS RELATING TO BILATERALITY IN OTHER FIELDS.
- 5 STUDIES RELATING TO BILATERAL INFECTED MODELS, 2024, 2013, 2006, 1991, 1993
- PAUCITY OF STUDIES
- 13 STUDIES OF UNINFECTED BILATERAL INJURY MODELS ALSO REVIEWED



- Schweser K, Bozynski CC, Stoker AM, et al. 2024. Bacteriophage Therapy for Acute Fracture-Related Infections: An Effective Treatment When Compared to Antibiotics In A Canine Model. *J Orthop Trauma*.
- Bilateral ulnar defects in a canine, inoculum *S. aureus*, plates, 3 weeks sampling and 4 interventions
- Antibiotic control group and bacteriophage therapy.
- Infusion apparatus utilized, complex interventions, ethical and welfare concerns.



## Recommendation

- Scientific assessments of mobility and functionality that likely go beyond established standards for single limb bone defect infection models as they pertain to animal welfare (need for euthanasia) and pain management (need for analgesic administration) should be included.
- The cumulative effect of all the defects on animal welfare with correctly applied analgesic treatment and animal management should not exceed the effect of a single infected defect. 3)
- The overall scientific rigor of the research should provide formal proof-of-concept.
- Assurances that there is a scientific justification for the use of a bilateral model and it is not being applied primarily for cost-effectiveness reasons.
- The research needs to comply with national and international regulations governing animal research, such as the Animal Welfare Act (AWA) in the United States, Directive 2010/63/EU in the European Union, and guidelines from organizations like the National Institutes of Health (NIH) and the World Organization for Animal Health (OIE).
- There are several other institutions that have published guidelines such as the ARRIVE (Animal Research Reporting of In-vivo Experiments) guidelines and those formulated by the Association for assessment and accreditation of laboratory Animal care.
- Ultimately, it behoves researchers to at least streamline and gain uniformity in unilateral animal models. Researchers should also strive for better techniques, outcomes and statistical powering before advancing into the realm of bilateral models.

**Level of Evidence:** Expert Opinion



## ❖ **Vote:**

**Agree            28; 70%**

**Disagree       0**

**Abstain        12; 30%**